Complete Summary

GUIDELINE TITLE

Medication-assisted treatment for opioid addiction in opioid treatment programs: Medication-assisted treatment for opioid addiction during pregnancy.

BIBLIOGRAPHIC SOURCE(S)

Medication-assisted treatment for opioid addiction during pregnancy. In: Batki SL, Kauffman JF, Marion I, Parrino MW, Woody GE, Center for Substance Abuse Treatment (CSAT). Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. p. 211-24. (Treatment improvement protocol (TIP); no. 43).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Opioid addiction during pregnancy

GUIDELINE CATEGORY

Management
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Psychiatry
Psychology

INTENDED USERS

Nurses
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers
Substance Use Disorders Treatment Providers

GUIDELINE OBJECTIVE(S)

To describe the complications associated with pregnancy and opioid addiction and how pregnancy should be addressed during medication-assisted treatment for opioid addiction (MAT) to reduce the potential for harm to a pregnant woman in MAT and her fetus

TARGET POPULATION

Pregnant women in medication-assisted treatment for opioid addiction (MAT)

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

1. Diagnosis of opioid addiction in pregnant patients
2. Medical and substance use histories
3. Physical examination
4. Drug test reports
5. Assessment of signs or symptoms of withdrawal
6. Assessment of other indications of addiction (diseases associated with drug use, poor attendance for prenatal care, and unexplained fetal growth abnormalities)
7. Laboratory tests

Management

1. Monitoring for medical and obstetrical complications
2. Support and counseling for human immunodeficiency virus (HIV) infected pregnant women
3. Patient education on adverse effects of substance use on their fetuses
4. Methadone dosage and management
    - Induction and stabilization
    - Split dosing
5. Management of polysubstance use

6. Management of acute opioid overdose in pregnancy (naloxone therapy)
7. Managing withdrawal from methadone
8. Postpartum treatment of mothers in medication-assisted treatment for opioid addiction (MAT)
9. Breast-feeding
10. Management of neonatal abstinence syndrome (NAS)
11. Use of buprenorphine during pregnancy
12. Integrated, comprehensive psychosocial services
13. Nutrition assessment, counseling, and assistance

MAJOR OUTCOMES CONSIDERED

- Complications of pregnancy
- Fetal morbidity and mortality rate
- Incidence of neonatal abstinence syndrome
- Perinatal morbidity and mortality
- Developmental sequelae associated with in utero methadone addiction
- Successful treatment outcomes
- Relapse rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search involved careful consideration of all relevant clinical and health services research findings, practice experience, and implementation requirements.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

After selecting a topic, Center for Substance Abuse Treatment (CSAT) invites staff from pertinent Federal agencies and national organizations to be members of a resource panel that recommends specific areas of focus as well as resources that should be considered in developing the content for the Treatment Improvement Protocols (TIP). These recommendations are communicated to a consensus panel composed of experts on the topic who have been nominated by their peers. This consensus panel participates in a series of discussions. The information and recommendations on which they reach consensus form the foundation of the TIP. The members of each consensus panel represent substance abuse treatment programs, hospitals, community health centers, counseling programs, criminal justice and child welfare agencies, and private practitioners. A panel chair (or co-chairs) ensures that the contents of the TIP mirror the results of the group's collaboration.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A large and diverse group of experts closely reviews the draft document. Once the changes recommended by these field reviewers have been incorporated, the Treatment Improvement Protocol (TIP) is prepared for publication, in print and on line.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Acceptance of Methadone Maintenance as the Standard of Care

Methadone has been accepted since the late 1970s to treat opioid addiction during pregnancy. In 1998, a National Institutes of Health consensus panel recommended methadone maintenance as the standard of care for pregnant women with opioid addiction. Methadone currently is the only opioid medication approved by the U.S. Food and Drug Administration (FDA) for medication-assisted treatment for opioid addiction (MAT) in pregnant patients. Buprenorphine is classified as a category C drug by FDA (i.e., one lacking adequate, well-controlled studies in pregnant women) and, at this writing, is not FDA approved to treat pregnant women, although several studies have found it safe and effective in this group. Even though it is a category C drug, buprenorphine may be used with pregnant patients in the United States under certain circumstances (see "Use of Buprenorphine During Pregnancy" below).

Effective medical maintenance treatment with methadone has the same benefits for pregnant patients as for patients in general. In addition, methadone substantially reduces fluctuations in maternal serum opioid levels, so it protects a fetus from repeated withdrawal episodes. Comprehensive methadone maintenance treatment that includes prenatal care reduces the risk of obstetrical and fetal complications, in utero growth retardation, and neonatal morbidity and mortality.

Diagnosing Opioid Addiction in Pregnant Patients

In the consensus panel's experience, some women who are opioid addicted do not acknowledge pregnancy readily, or they misinterpret early signs of pregnancy, for example, fatigue, headaches, nausea and vomiting, and cramps, as opioid withdrawal symptoms. Consequently, onset of pregnancy may cause these patients to increase their use of illicit opioids or other substances that do not alleviate their perceived withdrawal symptoms but expose their fetuses to increased serum levels of these substances.

Many women who are opioid addicted confuse the amenorrhea caused by their stressful, unhealthful lifestyles with infertility. They might have been sexually active for years without using contraceptives and becoming pregnant. The consensus panel has noted that, because methadone normalizes endocrine functions, it is not unusual for women in the early phases of MAT to become pregnant unintentionally, especially if they receive no counseling for this possibility.

Procedures for diagnosing opioid and other addictions in pregnant women should incorporate information from their medical and substance use histories, physical examinations, drug test reports, and observed signs or symptoms of withdrawal. Other indications of addiction may include evidence of diseases associated with drug use (e.g., hepatitis, bacterial endocarditis, cellulitis), poor attendance for prenatal care, and unexplained fetal growth abnormalities (e.g., intrauterine growth retardation). Using an opioid antagonist to diagnose addiction in pregnant women is absolutely contraindicated; inducing even mild withdrawal can cause premature labor or other adverse fetal effects.

Medical and Obstetrical Concerns and Complications

Pregnant women who abuse substances, including alcohol and nicotine, have a greater-than-normal risk of medical complications. These women should be monitored regularly for signs of anemia, poor nutrition, increased blood pressure, hyperglycemia, sexually transmitted diseases (STDs), hepatitis, preeclampsia, and other complications of pregnancy or health problems related to addiction. Good nutrition, including vitamin supplements, should be encouraged. Pregnant women should be educated about the potential adverse effects of substance use on their fetuses, such as fetal alcohol syndrome and premature labor associated with opioid withdrawal or stimulant use. Patient use of prescribed medications other than methadone should be monitored for compliance with usage directions and for adverse effects.

Chronic substance use in pregnancy can cause medical complications (some are listed in Exhibit 13-1 of the original guideline document), depending on how substances are administered and when or whether problems are identified and treated. Infections account for a high percentage of these complications in pregnant women who are opioid addicted, as they do in all people who abuse opioids. Infections can be profoundly harmful to both women and their fetuses, particularly if infections remain unrecognized and untreated during gestation. Hepatitis B and C, bacterial endocarditis, septicemia, tetanus, cellulitis, and STDs are especially frequent.

The rate of vertical perinatal transmission of hepatitis B virus (HBV) is high (ranging from 70 to more than 90 percent), especially if a pregnant woman has active infection (determined by a positive hepatitis B antigen test) in the third trimester or within 5 weeks postpartum. If a new mother's hepatitis B antigen test is positive, the neonate should receive both hepatitis B vaccine and hepatitis B immune globulin. The rate of perinatal transmission of hepatitis C virus (HCV) is lower than that of HBV, as discussed below; however, vaccines exist for hepatitis A virus and HBV but not for HCV. Recommended laboratory tests for pregnant women who are opioid addicted are listed in the table below.

Laboratory Tests for Pregnant Women Who Are Opioid Addicted*	
• Complete blood count with differential and platelets • Chemistry screen (potassium [K], sodium [Na], chloride [Cl], calcium [Ca], phosphorus [P], carbon dioxide [CO_2], creatinine, blood glucose, blood urea nitrogen, total bilirubin, total serum protein albumin) • Hepatic panel (liver function tests) • Hepatitis B surface antigen (full panel if positive) • Hepatitis C antibody • Rubella titer • Serology (Venereal Disease Research Laboratory or Rapid Plasma Reagin tests) • Sickle prep (if appropriate) • Blood type; Rh and indirect Coombs Varicella (if unsure of history) • Human immunodeficiency virus (HIV) (with	• Urine tests Urinalysis--routine and microscopic Urine culture and sensitivity Urine drug screen • Tuberculin skin test (Mantoux) • Alpha-fetoprotein between 15 and 21 weeks' gestation (optimal, 16 to 18 weeks) • 1-hour, 50 mg glucose

Laboratory Tests for Pregnant Women Who Are Opioid Addicted*	
counseling)	challenge test at 24 to 28 weeks' gestation (at initial visit if risk factors) • Repeat complete blood count and serology at 24 to 28 weeks' gestation • Group B Strep vaginal-rectal culture at 35 to 37 weeks' gestation

* Reprinted from Obstetrics and Gynecology Clinics of North America, 25(1), Kaltenbach et al., Opioid dependence during pregnancy. Effects and management, pp. 139-151, 1998, with permission from Elsevier.

HCV

Pregnant women with a history of injection drug use are at high risk for HCV infection and should be screened for anti-HCV antibody. HCV ribonucleic acid (RNA) testing should be performed if an anti-HCV antibody test is positive. The results facilitate referral for further evaluation, staging, and treatment of liver disease after delivery. Infants whose mothers have hepatitis C should receive HCV RNA testing along with antibody testing for HCV between ages 2 and 6 months and again between 18 and 24 months.

During pregnancy, HCV can be transmitted vertically from mother to fetus. However, multiple studies have shown low overall HCV vertical transmission risk and greater risk from factors such as HIV co-infection or high HCV viral load. Vaginal delivery and breast-feeding do not appear to increase the risk of neonatal HCV infection significantly. Available treatments to prevent vertical transmission, however, are limited by the fetal toxicity of the medications currently available for HCV infection.

HIV/Acquired Immune Deficiency Syndrome (AIDS)

Pregnant women who are opioid addicted and HIV positive present a unique treatment problem. A limited number of studies with small numbers of patients have examined the relationship of HIV, methadone, and immune function. These studies have not been replicated widely. Therefore, it is difficult to conclude any significant relationship involving HIV, methadone, and immune function until additional studies are completed. Studies on the combined effects of HIV antiretroviral treatment and methadone especially are needed.

The consensus panel recommends that women who are opioid addicted and HIV infected receive additional counseling and support during the postpartum period to improve their adherence to antiretroviral therapy and to meet the demands of caring for a newborn. Breast-feeding by HIV-infected women has been associated with an increased risk of HIV transmission and should be discouraged.

Obstetrical Complications

Obstetrical complications in pregnant women who are opioid addicted are the same as those seen at increased rates in all women who lack prenatal care (see Exhibit 13-3 in the original guideline document). These complications may be difficult to diagnose in patients who are opioid addicted because they often deny the existence of complications or avoid medical settings. When obstetrical complications are confirmed, standard treatments, including use of medications to arrest preterm labor, can be initiated safely.

Methadone Dosage and Management

The consensus panel recommends that methadone dosages for pregnant women be determined individually to achieve an effective therapeutic level.

Induction and Stabilization

Methadone dosages for pregnant women should be based on the same criteria as those for women who are not pregnant. Women who received methadone before pregnancy should be maintained initially at their prepregnancy dosage. However, if pregnant women have not been maintained on methadone, the consensus panel recommends that they either be inducted in an outpatient setting by standard procedures or be admitted to a hospital (for an average stay of 3 days) to evaluate their prenatal health status, document physiologic dependence, and initiate methadone maintenance if possible.

For pregnant women being inducted in an outpatient setting, a widely accepted protocol is to give initial methadone doses of 10 to 20 mg per day, with exact dosage based on a patient's opioid use history. A patient should be asked to return at the end of the day for follow-up evaluation, and the initial dose may be followed by regular adjustments of 5 to 10 mg based on therapeutic response. Twice daily observation should continue until the patient is stabilized. If evidence of intoxication or withdrawal emerges, treatment providers should adjust the patient's dosage immediately. Most pregnant women can be stabilized within 48 to 72 hours. In outpatient settings, where fetal monitors usually are unavailable, it is crucial that patients record measures of fetal movement at set intervals.

Split Dosing

Split-dosing methadone regimens are accepted widely for pregnant patients, but little empirical investigation has been done of its effects on fetuses or maternal plasma levels. Although split dosing may improve maternal compliance with treatment and decrease cocaine use, traveling to an opioid treatment program (OTP) twice a day or, for unstable or newly admitted patients, qualifying for take-home medication doses may be difficult.

Managing Polysubstance Use

A large percentage of pregnant women in MAT--up to 88 percent in one study--continue to use other substances including alcohol, nicotine, heroin, cocaine, barbiturates, and tranquilizers. The risks of other substance use for both maternal and fetal health are well documented. It is essential that patients be monitored for

use of both licit and illicit drugs and alcohol to manage appropriately the perinatal care of both mothers and infants.

Polysubstance use is a special concern during pregnancy because of the adverse effects of cross-tolerance, drug interactions, and potentiation and the serious maternal and fetal health risks from continued substance use and lack of adequate prenatal care.

Management of Acute Opioid Overdose in Pregnancy

Opioid overdose in pregnancy threatens both pregnant women and their fetuses. Naloxone, a short-acting, pure opioid antagonist, is the pharmacological treatment of choice for opioid overdose but should be given to pregnant patients only as a last resort. Patients should receive naloxone (0.01 mg/kg of body weight) intravenously after an airway is established to ensure adequate respiration. Patients can receive additional naloxone doses every 5 minutes after they regain consciousness. Naloxone's duration of action is from 30 minutes to 2 hours, depending on the dose and type of substance that was used, whereas that of most opioids is from 6 to 8 hours and that of methadone or other long-acting opioids (e.g., morphine sulfate contin, OxyContin®) is from 12 to 48 hours (or more for levo-alpha acetyl methadol). Therefore, symptoms are likely to recur within 30 minutes to 2 hours of naloxone treatment, and treatment providers should continue administering naloxone intravenously or intramuscularly at intervals until the effects of illicit opioids markedly diminish, which may take 2 to 3 days. Special care is needed to avoid acute opioid withdrawal that can harm a fetus. Treatment providers should titrate the naloxone dose against withdrawal symptoms and use a short-acting opioid to reverse acute withdrawal symptoms.

Managing Withdrawal From Methadone

Withdrawal from methadone, called medically supervised withdrawal (MSW) or dose tapering, is not recommended for pregnant women. When MSW is considered, however, a thorough assessment is important to determine whether a woman is an appropriate candidate for MSW because the procedure frequently results in relapse to opioid use. Appropriate patients for MSW during pregnancy include those who

- Live where methadone maintenance is unavailable
- Have been stable in MAT and request MSW before delivery
- Refuse to be maintained on methadone
- Plan to undergo MSW through a structured treatment program

A patient who elects to withdraw from methadone should do so only under supervision by a physician experienced in perinatal addiction treatment, and the patient should receive fetal monitoring. MSW usually is conducted in the second trimester because the danger of miscarriage may increase in the first trimester and the danger of premature delivery or fetal death may increase in the third trimester. However, the consensus panel has found no systematic studies on whether withdrawal should be initiated only during the second trimester. If MSW is undertaken, methadone should be decreased by 1.0 to 2.5 mg per day for inpatients and by 2.5 to 10.0 mg per week for outpatients. Fetal movement should be monitored twice daily in outpatients, and stress tests should be

performed at least twice a week; MSW should be discontinued if it causes fetal stress or threatens to cause preterm labor.

Postpartum Treatment of Mothers in MAT

Current treatment practices include continuing methadone after delivery either at dosages similar to those before pregnancy or, for women who began methadone maintenance during pregnancy, at approximately half the dosages they received in the third trimester. However, no empirical data support these approaches, and any decrease should be based on signs of overmedication, withdrawal symptoms, or patient blood plasma levels.

Breast-Feeding

Mothers maintained on methadone can breast-feed if they are not HIV positive, are not abusing substances, and do not have a disease or infection in which breast-feeding is contraindicated. Hepatitis C is no longer considered a contraindication for breast-feeding.

The American Academy of Pediatrics has a longstanding recommendation that methadone is compatible with breast-feeding only if mothers receive no more than 20 mg in 24 hours. However, studies have found minimal transmission of methadone in breast milk regardless of maternal dose. One study found only small amounts of methadone in breast milk of women maintained on daily doses up to 180 mg and argued that available scientific evidence does not support dosage limits of 20 mg a day for nursing women.

Effects on Neonatal Outcome

Neonatal Abstinence Syndrome (NAS)

Infants prenatally exposed to opioids have a high incidence of NAS, characterized by hyperactivity of the central and autonomic nervous systems that is reflected in changes in the gastrointestinal tract and respiratory system. Infants with NAS often suck frantically on their fists or thumbs but may have extreme difficulty feeding because their sucking reflex is uncoordinated. Withdrawal symptoms may begin from minutes or hours after birth to 2 weeks later, but most appear within 72 hours. Preterm infants usually have milder symptoms and delayed onset. Many factors influence NAS onset, including the types of substances used by mothers, timing and dosage of methadone before delivery, characteristics of labor, type and amount of anesthesia or analgesic during labor, infant maturity and nutrition, metabolic rate of the infant's liver, and presence of intrinsic disease in infants. NAS may be mild and transient, delayed in onset or incremental in severity, or biphasic in its course, including acute neonatal withdrawal signs followed by improvement and then onset of subacute withdrawal. Although NAS can be more severe or prolonged with methadone than heroin because of methadone's longer half-life, with appropriate pharmacotherapy, NAS can be treated satisfactorily without any severe neonatal effects.

Onset of NAS may be delayed by other neonatal illnesses. In addition, various other conditions may mimic NAS, such as hypoglycemia, hypocalcemia, sepsis,

and neurological illnesses. To rule out such conditions, infants suspected of having NAS should have a complete blood cell count with differential, electrolyte and calcium levels, comprehensive neurological consultation, and head ultrasound if indicated.

An abstinence scoring system should be used to monitor opioid-exposed newborns to assess the onset, progression, and diminution of symptoms. The Neonatal Abstinence Score is used widely to estimate NAS severity, determine whether pharmacotherapy is needed, and monitor the optimum response to therapy. All infants of mothers with an opioid use history should be scored every 4 hours. Control is achieved when the average Neonatal Abstinence Score is less than 8, infants exhibit rhythmic feeding and sleep cycles, and infants have optimal weight gains.

If pharmacological management is indicated, infants should be treated with neonatal opioid solution (0.4 mg/mL of morphine-equivalent solution; starting dosage, 0.4 mg/kg/dose given orally in six to eight divided doses [timed with the feeding schedule]). Dosage should be increased by 0.4 mg/kg/dose as needed until control is achieved or a maximum dosage of 2.0 mg/kg/day is reached. If Neonatal Abstinence Scores remain high but daily doses approach the maximum, the infant's symptoms should be reassessed and concurrent pharmacotherapy with phenobarbital considered.

When control is achieved, the dosage should be continued for 72 hours before pharmacological weaning begins, in which dosage is decreased 10 percent daily or as tolerated until 0.2 mg/kg/day is reached, when medication may be discontinued. Decisions about dosage decrease rate during pharmacological weaning should be based on Neonatal Abstinence Scores and daily weight and physical exams.

Maternal Methadone Dosage and Extent of NAS

The relationship between maternal methadone dosage and NAS has been difficult to establish, and the consensus panel believes no compelling evidence shows that methadone reduction avoids NAS. Although a number of investigators have reported significant relationships between neonatal withdrawal and maternal methadone dosage, most have found no such relationship.

See the original guideline document for a discussion of studies on perinatal outcomes and developmental sequelae of infants born to women maintained on methadone.

Use of Buprenorphine During Pregnancy

Buprenorphine use for pregnant women has not been approved in the United States, although it may be used with pregnant patients under certain circumstances (see below). It may be a safe and effective treatment for some pregnant women who are opioid addicted, but more research is needed.

In view of incomplete data and the absence of FDA approval for use of buprenorphine in pregnant patients, the consensus panel recommends that

buprenorphine be used only when the prescribing physician believes that the potential benefits justify the risks. For example, patients already maintained and stable on buprenorphine who become pregnant probably should continue on buprenorphine with careful monitoring. Pregnant women who are opioid addicted but cannot tolerate methadone, those for whom program compliance has been difficult, or those who are adamant about avoiding methadone may be good candidates for buprenorphine. In such circumstances, it should be clearly documented in the patient's medical record that she has refused methadone maintenance treatment or that such services are unavailable; that she was informed of the risks of using buprenorphine, a medication that has not been thoroughly studied in pregnancy; and that she understands these risks. When treating pregnant patients, treatment providers should use buprenorphine monotherapy tablets (Subutex®) because no work has been done on the effects of fetal exposure to sublingual naloxone in buprenorphine-naloxone combination tablets (Suboxone®) during pregnancy. Consensus panelists have found that a patient already maintained on buprenorphine-naloxone combination tablets who becomes pregnant can be transferred directly to buprenorphine monotherapy tablets.

See the original guideline document for a discussion of buprenorphine effects on NAS.

Breast-Feeding During Buprenorphine Treatment

Based on research data, particularly findings that buprenorphine is likely to be poorly absorbed by infants via the oral route, the consensus panel recommends that women maintained on buprenorphine be encouraged to breast-feed because of the benefits to infants and mother-child interaction. The panel recommends more research, particularly to confirm that infants absorb little buprenorphine during breast-feeding.

Importance of Integrated, Comprehensive Services

Pregnant women who are opioid addicted need comprehensive treatment services, including individual, group, and family therapy to address both the physiological and psychological effects of substance use and psychosocial factors. Psychosocial complications may include disruption of the mother-child relationship, guilt over the adverse effects of addiction on the family, and family adjustment when a newborn is retained in the hospital. Problems associated with domestic violence, financial support, food, housing, and childcare issues can be overwhelming to women in recovery and should be addressed. AIDS prevention, counseling, testing, and educational services should be available during prenatal and parenting classes. Services should be aimed at eliminating substance use, developing personal resources, improving family and interpersonal relationships, eliminating socially destructive behavior, and helping new parents cope with their environment.

Integrated services, whether on site or through linkages to other community-based agencies, encourage prospective patients to enter a treatment program and continue treatment. Services should be woman centered and directly address traumatic events. The array of services may include

- Special groups to address problems of pregnant women who are opioid addicted
- Available treatments for women addicted to opioids, including pharmacotherapies
- Education and discussion groups on parenting and childcare
- Special groups and services for children and other family members
- Couples counseling
- Case management and assistance in locating safe, affordable housing

Psychosocial Barriers

Women addicted to opioids typically face financial, social, and psychological difficulties that affect their options and treatment progress. Many have histories of negative experiences with the legal system or children's protective services that may cause them to be resistant to or noncompliant with treatment. Guilt and shame coupled with low self-esteem and self-efficacy can produce behaviors difficult for some staff members to tolerate, such as lateness, missed appointments, continued illegal drug use, and demanding or provocative behaviors. For successful treatment, care should be provided in a gender-specific, nonpunitive, nonjudgmental, nurturing manner, with attention to each patient's fears and cultural beliefs.

Contingency Management Treatment Strategies

Overall, studies have suggested that contingency management using positive rewards for desired behaviors may be an important adjunct to MAT for pregnant women. It is noteworthy that interventions such as voucher-based reinforcement therapy (VBRT) not only are compatible with MAT but address both continued substance abuse and poor program attendance.

Nutrition Assessment, Counseling, and Assistance

People with substance use disorders often are poorly nourished. Substances themselves may impair users' metabolism, interfere with nutrient availability, and affect appetite. However, other lifestyle factors associated with substance use play a significant role, including poverty, poor eating and exercise habits, lack of concern about nutrition and health, and diets restricted by physiological conditions.

Pregnancy is an opportune time to help women improve their health-related attitudes and behaviors. The consensus panel recommends that all pregnant patients in MAT receive

- An assessment of nutritional status, eating habits, and weight
- Education on appropriate diet and weight to meet optimal targets for the pregnancy
- Counseling to ensure that special nutrition-related medical and psychosocial problems are addressed--with high priority given to stopping or substantially reducing cigarette, alcohol, and other substance use with known adverse effects on fetuses
- Supplemental nutrients when nutritional needs cannot be met by diet changes
- Information about and referral to food assistance programs.

Nutritional Education for Pregnant Patients in MAT

Most pregnant women in MAT can benefit from nutritional guidance that encourages them to have wholesome, well-balanced diets consistent with their ethnic or cultural backgrounds and financial situations. Such guidance helps them understand how diet and substance use affect the fetus, pregnancy, labor and delivery, and breast-feeding.

OTPs wishing to assess patients' knowledge about nutrition might be interested in the U.S. Department of Agriculture's 22-page survey forms to ascertain respondents' knowledge of nutrition, food composition, labeling requirements, and serving sizes, as well as eating habits and attitudes.

Food Program Assistance for Pregnant Patients in MAT

Pregnant women in MAT who are nutritionally at risk or financially needy may be eligible for supplemental food assistance. Their school-age children also might qualify for school breakfast and lunch programs, as well as summer food programs. OTP counselors should be familiar with the services and requirements of each type of program and make appropriate referrals.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Recommendations are based on a combination of clinical experience and research-based evidence.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate treatment of pregnant women in medication-assisted treatment for opioid addiction (MAT) to reduce complications of pregnancy and improve neonatal outcomes
- Effective medical maintenance treatment with methadone has the same benefits for pregnant patients as for patients in general. In addition, methadone substantially reduces fluctuations in maternal serum opioid levels, so it protects a fetus from repeated withdrawal episodes. Comprehensive methadone maintenance treatment that includes prenatal care reduces the risk of obstetrical and fetal complications, in utero growth retardation, and neonatal morbidity and mortality.

POTENTIAL HARMS

Adverse effects of pharmacological therapy

CONTRAINDICATIONS

CONTRAINDICATIONS

Using an opioid antagonist to diagnose addiction in pregnant women is absolutely contraindicated; inducing even mild withdrawal can cause premature labor or other adverse fetal effects.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The opinions expressed herein are the views of the consensus panel members and do not necessarily reflect the official position of Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), or Department of Health and Human Services (DHHS). No official support of or endorsement by CSAT, SAMHSA, or DHHS for these opinions or for particular instruments, software, or resources described in this document is intended or should be inferred. The guidelines in this document should not be considered substitutes for individualized client care and treatment decisions.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Chapter 14, Administrative Considerations, in the original guideline document, covers the challenging administrative aspects of managing and staffing the complex and dynamic environment of an opioid treatment program (OTP). Successful treatment outcomes depend on the competence, values, and attitudes of staff members. To develop and retain a stable team of treatment personnel, program administrators must recruit and hire qualified, capable, culturally sensitive individuals; offer competitive salaries and benefit packages; and provide good supervision and ongoing training. Implementing community relations and community education efforts is important for opioid treatment programs. Outreach and educational efforts can dispel misconceptions about medication-assisted treatment for opioid addiction and people in recovery. Finally, the chapter provides a framework for gathering and analyzing program performance data. Program evaluation contributes to improved treatment services by enabling administrators to base changes in services on evidence of what works. Evaluation also serves as a way to educate and influence policymakers and public and private payers.

Refer to Chapter 14 in the original guideline document for full details (see "Companion Documents" field in this summary).

IMPLEMENTATION TOOLS

Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Medication-assisted treatment for opioid addiction during pregnancy. In: Batki SL, Kauffman JF, Marion I, Parrino MW, Woody GE, Center for Substance Abuse Treatment (CSAT). Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. p. 211-24. (Treatment improvement protocol (TIP); no. 43).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005

GUIDELINE DEVELOPER(S)

Substance Abuse and Mental Health Services Administration (U.S.) - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Treatment Improvement Protocol (TIP) Series 43 Consensus Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the National Library of Medicine Health Services/Technology Assessment (HSTAT) Web site. Also available in Portable Document Format (PDF) from SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI) Web site.

Print copies: Available from the National Clearinghouse for Alcohol and Drug Information (NCADI), P.O. Box 2345, Rockville, MD 20852. Publications may be ordered from NCADI's Web site or by calling (800) 729-6686 (United States only).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Executive summary. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. xvii-xx. (Treatment improvement protocol (TIP); no. 43).
- Introduction. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 1-10. (Treatment improvement protocol (TIP); no. 43).
- History of medication-assisted treatment for opioid addiction. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 11-23. (Treatment improvement protocol (TIP); no. 43).
- Pharmacology of medications used to treat opioid addiction. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 25-42. (Treatment improvement protocol (TIP); no. 43).
- Administrative considerations. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 225-240. (Treatment improvement protocol (TIP); no. 43).
- Appendix D: Ethical considerations in MAT. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 297-304. (Treatment improvement protocol (TIP); no. 43).

Electronic copies: Available from the National Library of Medicine Health Services/Technology Assessment (HSTAT) Web site. Also available in Portable Document Format (PDF) from SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI) Web site.

The following are also available:

- Knowledge Application Program. KAP keys for clinicians. Based on TIP 43: Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. 20 p. Electronic copies: Available in Portable Document Format (PDF) from the SAMHSA Web site.
- Quick guide for clinicians. Based on TIP 43: Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. 39 p.

Electronic copies: Available in Portable Document Format (PDF) from the SAMHSA Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on December 28, 2005. The information was verified by the guideline developer on January 23, 2006.

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